

REMARKS/ARGUMENTS

The Office is requiring an election of species and restriction to one of the following groups:

- Group I: Claims 1, 3-10, and 13-16, drawn to a product and a drug comprising said product;
- Group II: Claim 12, drawn to a process for making the product of Group I; and
- Group III: Claims 17-19, drawn to methods of using the product of Group I to treat various conditions.

Applicants elect with traverse Group I, Claims 1, 3-10, 13-16, for examination. In addition, Applicants provisionally elect with traverse, for examination purposes only, the following species:

- 1) cationized metalloporphyrin complex [5,10,15,20-tetrakis(2-methylpyridyl)porphyrin] ( $R^1$ - $R^4$  are 2-methylpyridyl); the metal is iron (Fe); the species can be found in Example 1 of the specification as filed;
- 2) anionic surfactant SAS (stearic acid); the species can be found in the paragraph beginning at page 5, line 18;
- 3) noisome-forming substance is mixture of Pluronic F-88 and cholesterol; the species can be found in the paragraphs beginning at page 6, line 10 and page 6, line 15.

The elected species encompass at least claims 1, 3-6, 8-10, and 13-16.

Restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a serious burden placed on the Office if restriction is not required (MPEP §803). The burden is on the Office to provide reasons and/or examples to support any conclusion in regard to patentable distinction (MPEP §803). Moreover, when citing lack of unity of invention in a national stage application, the Office has the burden of explaining why each group lacks unity with the others (MPEP § 1893.03(d)), i.e. why a single general inventive concept is nonexistent. The lack of a single inventive concept must be specifically described.

The Office alleges that Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding

special technical features for the following reasons: “The technical feature common to Groups I-III is a metalloporphyrin complex-embedding noisome, which is claimed to have anti-inflammatory properties. The prior art teaches that metalloporphyrin complexes have anti-inflammatory mechanisms and that anti-inflammatory therapeutic agents can be incorporated into niosomes. Therefore, there is not a special technical feature present which links the claims as defined by PCT Rule 13.2”

Annex B of the Administrative Instructions under the PCT, paragraph b (Technical Relationship), states, emphasis added:

The expression “special technical feature” is defined in Rule 13.2 as meaning those technical features that defines a contribution which each of the inventions, ***considered as a whole***, makes over the prior art. The determination is made on the contents of the claims as ***interpreted in light of the description*** and drawings (if any).

Applicants respectfully submit that the Office did not consider the contribution of each invention, ***as a whole***, in alleging the lack of a special technical feature. Applicants also respectfully submit that the Office has not provided any indication that the contents of the claims ***interpreted in light of the description*** were considered in making this allegation. Therefore, the Office has not met the burden necessary to support the assertion of a lack of unity of the invention.

In regard to the required election of species, Applicants make no statement regarding the patentable distinctness of the species, but note that for restriction to be proper, there must be a patentable difference between the species as claimed. MPEP § 808.01(a). The Office has not provided any reasons or examples to support a conclusion that the species are indeed patentably distinct. Accordingly, Applicants respectfully submit that the restriction is improper, and Applicants’ election of species is for examination purposes only.

For the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary in order to sustain the requirement for restriction. Applicants therefore request that the requirement for restriction be withdrawn.

Applicants respectfully submit that the above-identified application is now in condition for examination on the merits, and early notice thereof is earnestly solicited.

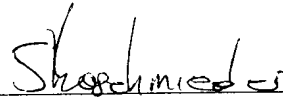
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Respectfully Submitted,

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